

Notice of Allowability

Application No.

10/735,538

Applicant(s)

BECOURT ET AL.

Examiner

Art Unit

Humera N. Sheikh

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06 April 2004.
2. ☒ The allowed claim(s) is/are 1 and 4-22.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 02/20/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 7/5/06
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Oath or Declaration filed 04/06/04 and the Information Disclosure Statement (IDS) filed 02/20/04 is acknowledged.

Claims 1 and 4-22 are pending in this application. Claims 1, 11 and 22 have been amended. Claims 2 and 3 have been cancelled. Claims 1 and 4-22 are allowed.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Balaram Gupta on July 05, 2006.

The application has been amended as follows:

In the Claims:

In **Claim 1**, in subsection (c), after the phrase 'an adsorbent agent', the following has been added: "**, wherein the cellulosic polymer and the methacrylic polymer are respectively ethylcellulose in an amount of from about 30% to about 50% by weight and a cationic polymer formed from 2-dimethylaminoethyl methacrylate and neutral methacrylates in an**

amount of from about 10% to about 25% by weight and wherein the alkaline agent and the adsorbent agent are respectively selected from the group consisting of meglumine, lysine, sodium and potassium citrate and sodium and potassium carbonate, and selected from the group consisting of magnesium aluminum silicate and talc.”

In **Claim 4**, the claim dependency has been changed from ‘claim 3’ to ‘claim **1**’.

In **Claim 11**, line 2, after the term “formulation”, the phrase “**according to claim 1**” has been added.

In **Claim 22**, line 2, after the term “product”, the phrase “**according to claim 1**” has been added.

Claims 2 & 3 have been cancelled.

Allowable Subject Matter

Claims 1 and 4-22 are allowed.

The following is an examiner’s statement of reasons for allowance:

The primary reasons for allowance are that the prior art does not disclose nor teach the instant taste-masking pharmaceutical formulation, wherein the cellulosic polymer is ethylcellulose provided in amounts of about 30% to about 50% and the methacrylic polymer is a cationic polymer formed from 2-dimethylaminoethyl methacrylate and neutral methacrylates provided in an amount of from about 10% to about 25% by weight. The prior art further fails to disclose or teach the instant taste-masking pharmaceutical formulation that includes an alkaline agent and an adsorbent agent chosen from the Markush grouping of instant claim 1.

The instant invention demonstrates an improvement over prior art formulations in that it provides for improved bioavailability of active ingredient, as well as effective taste masking of active ingredient.

In a telephonic interview held 07/05/06 between Applicant's representative and the Examiner, suggestions were made by the Examiner to incorporate the limitations of claims 2 and 3 into generic claim 1 and also to recite the amount ranges of the ethylcellulose (~30% - ~50%) and methacrylic polymers (~10% - ~25%) into claim 1 and canceling claims 2 & 3. Examiner also suggested amending independent process claims 11 and 22 by placing their dependency upon claim 1. Applicant's representative agreed to the amendments proposed by the Examiner. Accordingly, the instant invention is rendered patentable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh



Patent Examiner

TC-1600

Art Unit 1615

July 05, 2006

hns